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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,071	01/08/2001	Karl Tryggvason	TRV 20014 P	6472

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	16

DATE MAILED: 02/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/756,071	TRYGGVASON ET AL.	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) ~~1-3 and 7-11~~ 1-11 is/are pending in the application.

4a) Of the above claim(s) 4-6 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The amendment filed November 4, 2002 has been entered. The examiner acknowledges the amendments to the specification. Claim 1 has been amended. Claims 7-11 have been newly added. Claims 1-3 and 7-11 are under consideration in office action.

This application contains claims 4-6 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120.

Applicants assert that example 4 of the instant application was taken from the priority provisional application. However, the instant claims are drawn to a method for intervention of gamma2 chain interactions of invasive carcinomas with surrounding tissues by exposing an invasive carcinoma to anti-gamma2 chain antibodies against the gamma2-domain III of lamin-5 and not to a means for inhibiting the migration of cancer cells that is what the provisional is drawn to. There is no disclosure of a method for intervention of gamma2 chain interactions of invasive carcinomas with surrounding tissues by exposing an invasive carcinoma to anti-gamma2 chain antibodies against the gamma2-domain III of lamin-5. This feature has been first introduced in the instant

continuation-in-part application and thus such claims are entitled only to the filing date of the instant application.

Therefore, in the absence of support, thee benefit of the earlier filing date under 35 U.S.C. 120 of the parent application Serial No. 08/317,450, 08/800,593 and 60/175,005 has been denied for the claims of the instant application.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments:

a) the rejection of claims 1-3 under 35 U.S.C. 112, second paragraph,

Response to Arguments

4. Applicant's arguments filed November 4, 2002 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The written description rejection of claims 1-3 and 7-11under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons already of record.

The claims are drawn to a method for intervention of gamma2 chain interactions of invasive carcinomas with surrounding tissues by exposing an invasive carcinoma to anti-gamma2 chain antibodies against the gamma2-domain III of lamin-5.

However the method still fails to meet the written description provision of 35 UCS 112, first paragraph. The claimed method does not teach a method of intervention of all gamma2 chain interactions therefore the rejection is maintained.

Applicants points to pages 35-36 as written description support for the method of inhibiting cell migration using antibodies against the gamma2-domain III chain of lamin-5. However, it is the examiner's position that the specification does not provide written description support for a method for intervention of gamma2 chain interactions of invasive carcinomas with surrounding tissues, but rather for inhibiting cell migration. Applicants' showing is not persuasive.

There is no teaching of polyclonal or monoclonal antibodies used in a method for intervention of all gamma2 chain interactions of invasive carcinomas with surrounding tissues. A method for inhibiting cell migration is not equivalent to a method for intervention of gamma2 chain interactions of invasive carcinomas with surrounding tissues. There is no teaching of what interactions are being intervened.

Moreover, a skilled artisan cannot envision the detailed steps of the claimed method since the specification has not defined what the method steps are. There are no examples of using the method for intervention of gamma2 chain interactions of invasive carcinomas. There are no in vivo test that could correspond to said method. There is no

teaching of either polyclonal or monoclonal antibodies that intervene between gamma2 chain interactions of invasive carcinomas and the surrounding tissues.

Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression. The amino acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Currently the method for intervention of gamma2 chain interactions of invasive carcinomas with surrounding tissues by exposing an invasive carcinoma to anti-gamma2 chain antibodies against the gamma2-domain III of lamin-5 is insufficient to support the claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The specification does not provide a clear protocol by which the method for intervention could be practiced at the time the invention was made. In view of the lack of evidence in the specification as filed, it is apparent that one skilled in the art would recognize that applicants were not in possession, at the time of filing the instant application, of a method for intervention of gamma2 chain interactions of invasive carcinomas with surrounding tissues by exposing an invasive carcinoma to anti-gamma2 chain antibodies against the gamma2-domain III of lamin-5. The specification does not teach a representative example from which the method is based upon. As previously stated, applicants have not shown a method for intervention which is

sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. Thus a skilled artisan cannot envision said method and therefore conception cannot be achieved until reduction to practice has occurred. Therefore, the claims lack written description of a method for intervention of gamma2 chain interactions of invasive carcinomas with surrounding tissues by exposing an invasive carcinoma to anti-gamma2 chain antibodies against the gamma2-domain III of lamin-5. In view of the lack of written description of the claims, the full breadth of the claims fail to meet the written description provision of 35 USC 112, first paragraph and the rejection is maintained.

6. The rejection of claims 1-3 and 7-11 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons already of record.

The rejection is on the grounds that the specification is not enabled for a method for intervention of gamma2 chain interactions of invasive carcinomas with surrounding tissues by exposing an invasive carcinoma to anti-gamma2 chain antibodies against the gamma2-domain III of lamin-5.

Applicants points to pages 35-36 as written description support for the method of inhibiting cell migration using antibodies against the gamma2-domain III chain of lamin-5.

The specification at page 31 teaches a migration assay using a modified Boyden chamber assay wherein specific cells were placed in the upper compartment, medium with and without chemo attractants was used; the antibody was added to the compartment, the filters were removed, fixed and stained; the non-migrating cells were removed from the upper surface and the migration of cells was quantified. A transwell assays was also performed. The in vitro results show cells migration decreased to about 35-45%, and the use of both antibodies inhibited migration to about 50%. It is noted that there are no in vivo experiments. There are no experiments that teach a method for intervention of gamma2 chain interactions of invasive carcinomas with surrounding tissues by exposing an invasive carcinoma to anti-gamma2 chain antibodies against the gamma2-domain III of lamin-5. The claimed method lacks steps to determine the intervention of gamma2 chain interactions simply be exposing an invasive carcinoma to anti-gamma2 chain antibodies against the gamma2-domain III of lamin-5. There is no teaching of what interactions are being intervened and it is noted that intervention of interactions is significantly broader than inhibiting cell migration by 35-50%. Thus there are no examples of the claimed method and applicants have not pointed to support in the specification that supports the claimed methods. There are no in vivo examples. There are no working examples of using the method for intervention of gamma2 chain interactions of invasive carcinomas. None of these considerations have been contemplated in the specification, and in absence of these considerations, the rejection is maintained.

In absence of further guidance or support from Applicants, the skilled artisan would have to discover what the appropriate antibodies, reagents and method steps would be. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use of the claimed method. The claimed method would not predictably result in an enabled method for intervention. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict a method that would result in the desired method for intervention. Accordingly, one of skill in the art would be required to perform undue experimentation. Therefore, applicants' amendments have not overcome the rejection and one skilled in the art could not make and/or use the invention without undue experimentation.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

January 30, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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